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# Come On In, The Water's Fine: FDA Should Fully Embrace Remote Inspections

by Steve Silverman

Former US FDA device center compliance chief Steve Silverman argues in this opinion piece that the agency and stakeholders should take steps now to develop a remote-inspection framework for medical device manufacturers.

The COVID-19 pandemic produced a near endless list of challenges for the US Food and Drug Administration, including how to handle medical device facility inspections. As the pandemic showed, the FDA struggles with inspections when its operations are disrupted. This acutely affects foreign inspections as well as domestic ones. And the impact spans inspection types, from preapproval, to surveillance, to for-cause.

But rather than bemoaning FDA struggles, let's focus on fixes. There's a solution to suspended live inspections: inspecting remotely. These are inspections where agency investigators are not physically present. Rather, they use remote technology – like file sharing, video links and remote-control cameras – to review written materials and check facility operations.

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Let's be clear: I'm not suggesting that remote inspections work all the time. They're instead a new and important arrow for the FDA's quiver. The agency decides when to use remote inspections. But stakeholders like device makers know a lot too; they understand their sites, their personnel, and technical possibilities. So the best way forward is for FDA and these stakeholders to collaborate on when and how to use remote inspections.

### *Cui Bono*? FDA!

I've watched a lot of "Law and Order" – I'm not particularly proud of that – and it's taught me to always ask *cui bono*: who benefits? There's no question that properly executed remote inspections benefit device makers, whether through one-and-done visits, lower costs or inspection speed. But the FDA benefits too.

Remote inspections allow the agency to do more work in more places than it could before. Even pre-COVID-19, in-person inspections were tough. Travel costs, staff availability, time constraints, unexpected interruptions – all of these factors complicated inspections, and all of these factors are worse for inspections outside the US.

Remote inspections shrink these barriers. For example, visa requirements mean that foreign inspections must be planned – and announced – far in advance. This complexity disappears when an FDA investigator sits in their office, engaging by video. Plus, eliminating travel time means cost savings and greater staff availability. This means more inspections in more locations.

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As important, remote inspections sync the FDA with foreign regulators, including Australia, the UK, Japan and parts of Europe, that operate remotely. But the US has avoided this approach. This disparity leads to strange results. Imagine a device company with sites in the US and Japan. The sites make the same product and they use the same processes. Japanese regulators inspect remotely to gain a full picture of manufacturing practice; the FDA completes in-person inspections unpredictably and sometimes with delays. It's hard to explain these different outcomes, apart from the agency's resistance to remote inspections.

Even if you reject this scenario, what about the Medical Device Single Audit Program? MDSAP – which the FDA supports and includes agency staff – uses remote audits to evaluate US facilities. What is the case for mandating in-person FDA inspections when MDSAP audits of the *same sites* happen remotely?

It's also important to note that the FDA has used *Remote Regulatory Assessments* to test the remote-inspection waters. RRAs allow the agency to request delivery of a site's quality system records. These records are delivered outside of an inspection, and RRAs are not inspections: participation is voluntary, the FDA does not provide a list of observations (Form-483), and there

are no sanctions for a "poor" RRA.

This is a good start, but RRAs raise some basic questions. How can a regulatory professional sell an RRA to their managers? Why should a firm participate when it almost certainly will be inspected later (and now that inspection will be informed by an RRA)? And if the RRA broadens FDA oversight with unclear benefit, why would companies agree to it?

Most manufacturers want to do right by patients and the FDA, making high-quality devices that meet regulatory requirements. But these same companies also mitigate risks and control costs. This means, when appropriate, treating agency interactions as inspections, not as inspection "appetizers." When the FDA shows up, companies should give investigators the information they need and substantively answer their questions. Often, this *is* the inspection and the FDA should treat it as such.

## What's Next?

So where do we go from here?

The FDA should develop a remote-inspection framework. But not just the FDA; interested stakeholders should be at the table because they, working with the agency, will reach the best solution. Stakeholders means device makers, and it means payers, health care providers and patients. There are myriad examples of the FDA gathering such stakeholders to develop and implement innovative fixes.

Collaboration is likewise critical if remote inspections require a statutory fix. Whether the FDA needs formal authority to conduct remote device inspections is a question that I'll happily leave for another day. For now, let's just assume that it does. The timing is auspicious: the FDA is *negotiating device user fees*, which opens the door for legislative riders. These could include remote-inspection authority, and the case for this authority is strongest when all stakeholders back it.

Will remote strategies solve all inspection-related troubles? No. But let's take our wins where we can get them. Remote inspections will do a lot of good, not the least of which is aligning the FDA with its stakeholders. Based on this and other benefits, that's an effort worth making.